REMARKS

By this amendment, claims 154-155, 163-165, 168-182, 184 and 195 have been canceled without prejudice to resubmission. New claims 205-210 have been added. Upon entry of this amendment, claims 153, 156-162, 166-167 and 183, 185-194 and 196-210 will be pending in the present application.

Claim 153 has been amended to incorporate the limitations of claim 155 therein and to address certain objections/rejections raised by the Examiner, as discussed below. Claim 153 has also been amended to require that the sugar cane-derived extract contain less saccharide than the raw material from which it is extracted. Basis for this amendment is found at least in Example 3 on page 49, line 13 of the application as originally filed. The same types of amendments have been made to corresponding claims 183 and 194.

Claim 156 has been amended to rewrite this claim in independent form by incorporating all of the limitations of base claim 153 and intervening claim 154 therein. In addition, similar amendments were made to claim 156 as to claim 153, as discussed above. The same types of amendments have been made to corresponding claims 185 and 196.

New claims 205-210 correspond to claims 166-167, 192-193 and 203-204, respectively, and thus no new matter has been added.

The 35 U.S.C. 112 Rejections

Claims 153-204 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement on the basis that the term, "including one or more non-saccharides" is not supported by the specification as originally filed. Although the applicant does not concede the correctness of this rejection, the applicant has amended the claims to delete this phrase from all claims in order to obviate the rejection and expedite prosecution of the application to allowance. Specifically, this phrase has been deleted from independent claims 153, 183 and 194. Favorable consideration and withdrawal of the rejection in view of the claim amendments is requested.

Claims 153-204 have also been rejected under 35 U.S.C. 112, first paragraph on the basis that the specification does not reasonably provide enablement for treating any disease caused by any bacteria, fungus or virus. This rejection is respectfully traversed, at least insofar as it applies

to claims 153, 156-162, 166-167, 183, 185-194 and 196-204, as amended, as well as new claims 205-210, and reconsideration is requested for the reasons that follow.

Although the applicant does not concede the correctness of this rejection, the applicant has amended independent claims 153 and 156 to limit these claims to remedying an *Escherichia coli* infection. Claims 153 and 156, as amended, as well as all claims which depend therefrom, are enabled at least by Test Example 2 and Examples 1 and 3 of the specification as originally filed, which show effectiveness of the claimed method against an *Escherichia coli* infection.

The applicant has also amended independent claims 183, 185, 194 and 196 to limit the claimed method to remedying a Pseudorabies infection. Claims 183, 185, 194 and 196, as amended, as well as claims dependent therefrom, are enabled at least by Examples 2 and 4 of the application as originally filed, which show effectiveness of the claimed method against a Pseudorabies infection. Favorable consideration and withdrawal of the rejection is requested.

Claims 153-204 have been rejected under 35 U.S.C. 112, second paragraph, as indefinite. Specifically, the Examiner alleges that the phrase, "providing a remedial effect for a disease" is indefinite. This rejection is respectfully traversed and reconsideration is requested for the reasons that follow.

Although the applicant does not concede the correctness of this rejection, by this amendment, the applicant has deleted all references to "providing a remedial effect" from the claims in order to obviate this rejection and expedite prosecution of the application to allowance. The claims have been amended to require that the claimed method "remedy the disease." Basis for this amendment can be found, for example, on page 23, lines 20 to 25, where it states that, "The present invention may be applied to prevent or remedy diseases caused by weakness or deficiency of immunological function through control of immunological function of man or animals. The present invention may be applied also to prevent or remedy various kinds of infectious disease." Skilled persons are aware of the meaning of remedying a disease selected from an *Escherichia coli* infection and a Pseudorabies infection and thus the claims are in compliance with 35 U.S.C. §112, second paragraph. Favorable consideration and withdrawal of the rejection is requested.

Claims 153, 168, 183 and their dependents have been rejected under 35 U.S.C. 112, second paragraph, as indefinite. Specifically, the Examiner alleges that the phrase, "including one or more non-saccharides" is indefinite. This rejection, at least insofar as it applies to the

claims, as amended, is respectfully traversed and reconsideration is requested for the reasons that follow.

Although the applicant does not concede the correctness of this rejection, by this amendment, the applicant has deleted all references to the phrase "including one or more non-saccharides" from the claims in order to obviate this rejection and expedite prosecution of the application to allowance. Favorable consideration and withdrawal of the rejection are requested.

The Rejection Under 35 U.S.C. §102

Claims 153-154, 168-169 and 183 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/02041 (Bermudez et al.) (hereinafter referred to as "Bermudez"). Claims 154 and 168-169 have been canceled without prejudice to resubmission thereby obviating the rejection of these claims. This rejection, at least insofar as it applies to claims 153 and 183, as amended, is respectfully traversed and reconsideration is requested for the reasons that follow.

The limitations of claim 155 have been incorporated into claim 153, thereby rendering claim 153 novel over Bermudez et al. since claim 155 was not rejected under 35 U.S.C. §102(b) over Bermudez et al. The limitations of claim 184 have been incorporated into claim 183, thereby rendering claim 183 novel over Bermudez et al. since claim 184 was not rejected under 35 U.S.C. §102(b) over Bermudez et al. Favorable consideration and withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. §103(a)

Claims 153-204 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bermudez, Kawai, Saska, Agar, Brewer and Kearny. This rejection, at least insofar as it applies to claims 153, 156-162, 166-167 and 182-183, 185-194 and 196-204, as amended, is respectfully traversed and reconsideration is requested for the reasons that follow.

Bermudez discloses a method for preparing compositions useful in anti-adhesive therapies, comprising two heating steps (ii)-(iii) as seen on page 3, lines 1 to 10 and page 5, lines 12 to 27 of Bermudez. Heating step (ii) heats the filtered liquid extract at a temperature of from about 60°C to about 70°C for a time period of about 30 to about 60 minutes. Heating step (iii) heats the liquid extract obtained in heating step (ii) at a temperature of from about 130°C to about 165°C for about 24 hours. Bermudez also discloses that it is important that the extract

reach a temperature of at least 150°C (i.e. the boiling point) as seen on page 5, lines 26 to 27 of Bermudez. The resulting product, Bercedin, is described on page 6 of Bermudez.

The Examiner takes the position that, "Bermudez teaches methods for treating bacterial, fungal and viral infections, the method comprising administering effective amounts of sugar cane extracts with amino acids." See page 9, lines 18-20. The applicant respectfully disagrees with this conclusion for the following reasons.

First, the passage relied on by the Examiner on page 2 of Bermudez actually reads, "The present invention provides therapeutic compositions, preferably derived from sugar cane, which contain primarily saccharide and amino acid components..." (emphasis added). See p. 2, lines 20-21 of Bermudez. Thus, page 2 of Bermudez does not teach administration of either sugar cane extracts or amino acids, but rather, teaches administration of (1) saccharide components, and (2) amino acid components. This is a very important distinction as explained below.

Page 4 of Bermudez, also relied on by the Examiner, teaches that, "The compositions are preferably derived from sugar cane by extraction and heating of the extract in a non-fermentation process." See page 4, lines 4-5 of Bermudez. Thus, the sugar cane extract is heated by a non-fermentation process to obtain the Bercedin composition that Bermudez discloses as being administered to humans and animals.

From the Summary of the Invention on page 3, lines 8-9 of Bermudez, it is learned that this heating step involves, "(iii) heating the filtered liquid extract at a temperature of from about 130°C to about 165°C for about 24 hours, under agitation." Sugar cane extract, when heated to temperatures in excess of 130°C, undergoes three important chemical changes. These changes are as follows:

(1) At least some sucrose is converted to the reducing sugar glucose,

(2) glucose condenses with amino acids to produce N-glucosylamines via the well-known Maillard reaction, and

(3) saccharides in the sugar cane extract polymerize.

Therefore, the Examiner's statement that Bermudez teaches administration of a sugar cane extract to humans or animals is not correct since what is actually taught by Bermudez is the administration of a composition obtained by chemically reacting a sugar cane extract under conditions of high temperature for an extended time period. Therefore, the sugar cane extract of Bermudez has been chemically changed in three significant ways by the heating step (iii).

Moreover, it is apparent to the skilled person that the reference to "saccharide components" in Bermudez refers to saccharide polymers of various sugar cane-derived monomers. This is apparent because Bermudez teaches, on page 2, lines 23 to 25 that, "it is believed that heat polymerization of one or more components of the sugar cane extract is required to develop the therapeutic activity of the composition."(emphasis added). Therefore, it is seen that one or more heat polymerized carbohydrates or polysaccharides, and not the unpolymerized saccharides contained in a sugar cane extract, are the active components in the Bercedin composition of Bermudez.

It is also apparent to a skilled person that the reference to "amino acid components" is a reference to reaction products of amino acids and not a reference to amino acids per se. This is confirmed by the Table on page 6, lines 3-19 of Bermudez which does not specify amino acids as a component of the Bercedin composition, but rather only specifies lectin and other amino acid-containing molecules, i.e. reaction products of amino acids with other materials from heating step (iii).

Since the sugar cane extract of Bermudez undergoes three significant chemical reactions prior to being administered to humans or animals, this composition clearly does not meet the requirement of claims 153, 166-167, 183, 192-194 and 196-204, that the composition be obtainable by passing a raw material selected from the group consisting of sugar cane juice, a liquid extract from sugar cane, and sugar cane-derived molasses, through a column packed with a synthetic adsorbent as a fixed carrier, and eluting substances adsorbed on the synthetic absorbent with a solvent selected from the group consisting of water, methanol, ethanol and mixtures thereof. Clearly, the composition of Bermudez is not obtainable in this manner since a severe heating step is required to develop the active ingredients of the composition of Bermudez by polymerization of the saccharides, as discussed above. Accordingly, Bermudez does not teach or suggest the administration of the composition of any of claims 153, 166-167, 183, 192-194 and 196-204.

Kawai, Saska, Brewer and Kearney all relate to various aspects of the sugar cane extract manufacturing process. However, none of these references provides any teaching or suggestion which would lead a skilled person to modify the process for making the composition of the primary reference, Bermudez, to eliminate the heating step (iii). As a result, any combination of Bermudez with Kawai, Saska, Agar, Brewer and Kearney still differs from the present invention

in that the Bercedin of Bermudez has undergone three chemical reactions, including polymerization of the saccharides. In fact, such a modification of the teachings of Bermudez would not be obvious since, as discussed above, Bermudez contains a clear teaching that, "...heat polymerization of one or more components of the sugar cane extract is required to develop the therapeutic activity of the composition."(emphasis added). See Bermudez at page 2, lines 23 to 25. Thus, the skilled person would not eliminate heating step (iii) of Bermudez since the expectation would be that the resultant composition would not have the desired therapeutic activity.

Moreover, a skilled person would not combine Bermudez with Kawai since Kawai teaches that the temperature of the sugar cane extract should be kept at or below 120°C. See e.g. p. 4, lines 21 and 55 of Kawai. Bermudez, on the other hand, requires temperatures above 130°C in order to develop the therapeutically active ingredients by heat polymerization. This would lead a skilled person away from a combination of Kawai with Bermudez since a skilled person would realize that the compositions of Kawai and Bermudez are clearly different due to the heat polymerization step (iii) of Bermudez, which is to be avoided in Kawai. As a result, it is not obvious to combine the method of Bermudez with the secondary reference to Kawai.

Saska et al. relates to a process for the separation of inositols from sugars and sugar alcohols. Saska et al. applies its process to raw sugar cane extract or an almond hull extract. See col. 1, lines 8-10. A skilled person, reading Saska et al. would not be motivated to apply the process of Saska et al. to the Bercedin of Bermudez since: (1) the Bercedin of Bermudez is not a raw sugar cane extract since it has been treated by a multi-step process including a high temperature polymerization step, and (2) there is no indication that the Bercedin of Bermudez contains inositol.

Agar et al. relates to a process for the separation of lignins from fibrous plant materials. The skilled person would not be motivated to apply this process to the Bercedin of Bermudez, as suggested by the Examiner, since there is no indication that the Bercedin of Bermudez contains lignins. Thus, the skilled person would have no reason to apply the separation process of Agar et al. to the Bercedin of Bermudez.

Therefore, for the foregoing reasons, the subject matter of claims 153, 166-167, 183, 192-194 and 196-204 is clearly unobvious over Bermudez et al. taken in combination with any of Kawai, Saska et al. Agar et al., Brewer or Kearney.

With regard to the remaining claims 156-162 and 185-191, each of these claims requires that the sugar cane-derived extract is:

(1) a fraction which absorbs light of a wavelength of 420 nm obtainable by column chromatographic treatment utilizing differences in affinity for an ion exchange resin packed in a column as the fixed carrier, and

(2) the sugar cane-derived extract must contain less saccharide than a composition from which the sugar cane-derived extract is extracted.

Thus, the subject matter of claims 156-162 and 185-191 differs from the teachings of Bermudez in at least two important aspects:

(1) the Bercedin of Bermudez is not a fraction which absorbs light at a wavelength of 420 nm since the Bercedin of Bermudez has not been fractionated, and

(2) the Bercedin of Bermudez is not a sugar-cane derived extract which contains less saccharide than a composition from which the extract was extracted since the Bercedin of Bermudez has not been subjected to extraction.

The Examiner takes the position that the teaching on page 10 of Bermudez that the Bercedin can be fractionated renders the present invention obvious. However, even if a skilled person follows the teachings on page 10 of Bermudez and fractionates the Bercedin of Bermudez, two elements of the claimed subject matter are still missing, namely,

(1) there is no teaching in Bermudez to select a fraction which absorbs light at a wavelength of 420 nm, and

(2) there is no teaching in Bermudez of the desirability of obtaining an extract which contains less saccharide than a composition from which it is extracted.

In fact, the skilled person would be led away from element (2) by Bermudez, since Bermudez teaches that the saccharides are the therapeutically active components of the Bercedin composition and thus the skilled person would want to maximize the amount of the saccharides for this reason.

None of the secondary references to Saska et al. Agar et al., Brewer or Kearney teaches elements (1)-(2) and thus these secondary references cannot cure the deficiencies of the primary reference to Bermudez.

With respect to the Kawai et al. reference, the skilled person would not combine Kawai with Bermudez for the reasons given above, namely, that Kawai et al. desires to prevent

polymerization of the saccharides by maintaining temperatures below 120°C, whereas Bermudez desires polymerization of saccharides and thus includes heating step (iii). Also, although Fig. 2 of Kawai references absorption of light at 420 nm, Kawai does not teach or suggest that by selecting an extract that absorbs light at 420 nm, a product could be obtained having beneficial effects against a disease caused by either an *Escherichia coli* infection or a Pseudorabies infection. Rather, Kawai only suggests that its products can be used as deodorizing compositions. Accordingly, favorable consideration and withdrawal of the rejection of claims 156-162 and 185-191, as amended, is requested.

Finally, in the Final Rejection on page 11, last paragraph the Examiner alleges that the claims read on eating sugar because the claimed extracts are obtained by the same methods practiced by the references to obtain sugar. The claimed method, as claimed in the amended claims, clearly does not read on eating sugar because the claimed method expressly requires that the sugar cane-derived extract which is administered must contain less saccharide than the material from which it is extracted. This claim limitation clearly differentiates the present invention from eating sugar since methods practiced to obtain sugar from sugar cane will increase the saccharide content of the material, since the saccharides are the desired product of such methods. In contrast, the claims of the present application all require that the saccharide content be decreased by the extraction process, thereby clearly differentiating the extraction process and resultant product of the present invention from extraction processes used to obtain sugars (saccharides) from sugar cane and the resultant sugar products.

Favorable consideration, entry of the amendment and issuance of a Notice of Allowance are solicited. Should the Examiner have any questions she is encouraged to call the Applicant's representative listed below.

Respectfully submitted,

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